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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,493	07/19/2000	Norman Nashed	SCH-1686-C1	1582

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EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/619,493	NASHED, NORMAN	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3-13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3-13 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

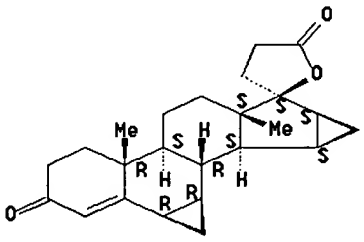
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Non-Final Office Action

This application is a division of 09/331,397, filed on 6/21/1999 (now abandoned), which is a 371 of PCT/DE97/03032, filed on 12/22/1997. Presently claimed invention after amendments is drawn to the method of treating premenstrual dysphoric disorder (PMDD) by administering drospirenone alone or in combination of estrogens.



Drospirenone

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/22/04 has been entered.

Rejection under 5 U.S.C. 112, first paragraph is withdrawn because claims are now amended to limit gestagen. Claims 1, 3-13 and 15-23 are pending and rejected. Amendments are entered. No claim is allowed.

Applicant's arguments and declaration filed Dr. Marie L. Foegh on 4/22/04 has been fully considered but was not found persuasive mainly for the following reasons:

1. Certain psychiatric disorders are excluded in the study; see the last paragraph on page 1 of the declaration. Examiner notes, that all the symptoms, which are cited in the specification as PMDD disorders, are listed in Table 1 on page 1619 of Dennerstein et al. This means prior art does not say specific wordings "PMDD" but includes all the issues of PMDD in the "menstrual distress questionnaire". See lines 9-18 on page 1619 (left side column). This is clear that gestagen used by the prior art was treating all the symptoms or at least some symptoms.

2. The declaration on page 4 discloses the results of DRSP and placebo. No other gestagen is compared.

3. In conclusion the declaration recites that "the study showed a highly significant treatment effect on PMDD of DRSP and ethinyl estradiol.. The effect size of DRSP+ E2 on the symptoms associated with PMDD exceeds that seen with placebo using the same and similar instruments." This is not considered unexpected results. These results are not compared with any closest prior art, such as progesterone alone and in combination with estrogen.

Applicant is requested to explain if there is any comparative data of improvement. The examiner also considered again the previous declaration filed by applicants.

. Applicant is also requested to explain what is formula 1 in line 16 on page 6 of the specification?.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-13 and 15-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dennertein et al. (British Medical Journal, Vol. 200, pages 1617-1621), and Johan Gullberg.

These two references cited teach the method, which embraces instantly claimed invention. See the entire documents especially in Dennertein, which discloses a trial and effects of progesterone and premenstrual symptoms see Table I on page 1619 and Table III on page 1620. Table I on page 1619 shows a list of premenstrual complaints reported by number of women. It should be noted that irritability is at the top of complaint list. Irritability is also a PMDD symptom and various symptoms of PMS and PMDD overlap.

In Denneratein et al. the data as shown in Tables II and III clearly shows significance of progesterone treatment (pages 1619 and 1620. See also "discussion" on page 1620, where progesterone treatment is favored. See Table 2.1 on page 12-13 and figure 8.2 on page 43 in Gullberg reference which teaches the Mood Changes and Menstrual Symptoms with different Gestagen/Estrogen combinations"

Instant claims differ from the reference in claiming a gestagen For example treatment of PMDD by gestagen and combination with estrogen, natural or synthetic wherein specific estrogen and estrogen are claimed for the treatment.

It would have been obvious to one skilled in the art to prepare compositions for the treatment of premenstrual symptoms as the above-cited references teach the treatment with gestagen and with combination of gestagen and estrogen. The studies show positive effects of the treatment. Therefore, the disclosure of the cited references obviously would lead a person skilled in the art to use the conventional known gestagens or in combination with estrogen.

Example shown in the specification does not specifically shows any unexpected results, which were not taught by the prior art. Even though PMS and PM DD are distinct as applicant argue however, PMDD is considered a severe form of PMS. Since the method for treating is used to treat PMS, (see especially Table 1 in Denneratein. Applicants must distinctly show if there is any superiority of the claimed invention.

Claims 1, 3-13 and 15-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Harvard Rev. Psychiatr. Vol. 2, No. 5, (1995), pages 233-245. The reference teaches treatment of PMDD by progesterone or oestrogen, which embraces Applicant's claimed invention. See the entire document especially page 234, right column and 235-236.

Clinical trials controlled studies are shown to have positive effects on symptoms such as irritation, anxiety, depression etc. In addition to effect of progesterone, the reference also discloses the positive effects of oestrogen, for PMDD treatment. See page 235-236.

The studies showed that subcutaneous or transdermally administered oestradiol improves a number of PMDD-related symptoms.

It would have been obvious to one skilled in the art at the time of invention to use the gestagens or oestrogen for the treatment of PMDD as taught by the prior art. In view of the teachings of the prior art of record cited above, a person skilled in the art would also consider administering a combination of the individual substances i.e. any gestagen and oestrogen for the treatment of PMDD for the reasons cited above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571)-272-9197. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/9/04

SABIHA QAZI, PH.D
PRIMARY EXAMINER